In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-1V

COREY SILVERS,	*	
	*	Chief Special Master Corcoran
Petitioner,	*	Filed: April 25, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Timothy McCarthy, Nutt Law Office, Louisville, KY, for Petitioner.

James V. Lopez, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On January 2, 2020, Corey Silvers filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioner alleges that an influenza ("flu") vaccine he received on October 15, 2018, caused him to experience a right shoulder skin abscess associated with a bacterial infection. *Id.* Although the matter was originally assigned to the "Special Processing Unit" ("SPU"), since it appeared to assert a claim likely to be easily settled, questions about the claim's fundamental viability resulted in its transfer to my regular docket.

[1] As provided by 42 U.S.C. § 300aa-12(d)(4)(B), the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

The parties dispute whether Petitioner has articulated a cognizable claim under the Vaccine Act, since the injury in question appears solely attributable to negligence unrelated to the effects of the vaccine's intended components. To that end, they have filed briefs in support of their positions. *See* Respondent's Motion to Dismiss, dated September 9, 2021 (ECF No. 28) ("Mot."); Petitioner's opposition, dated September 21, 2021 (ECF No. 29) ("Opp."); Respondent's Reply, dated October 7, 2021 (ECF No. 31) ("Reply"). There are unresolved legal questions as to whether the Act encompasses claims of negligence wholly unrelated to a vaccine's potentially-adverse effect on the human body. Nevertheless, I find that prior Program treatment of comparable claims not only supports the claim's legitimacy, but allows for an entitlement finding in the Petitioner's favor.

I. Fact History

I note at the outset that the parties do not meaningfully disagree as to the facts at issue—or the background matters (which I have only summarized below) relevant to the claim. *See* Mot. at 2–12; Opp. at 2–10. There are thus no factual issues to be developed herein, via expert input or otherwise.

Petitioner's Vaccination and Subsequent Reaction

On October 15, 2018, Petitioner received a flu vaccine administered by personnel employed by "Location Vaccination," a Kentucky-based business that contracted with other entities in a three-state region to provide on-site vaccine clinics. Ex. 8 at 1; Ex. 10; Ex. 13 at 3, 5. There is no filed medical record evidence of any immediate reaction to the vaccine in the two months thereafter. However, Petitioner received communication in late-December 2018 from his primary employer, informing him that other employees had reported reactions after receipt of vaccines administered by Location Vaccination. Ex. 5.

The following month (January 2019), Petitioner went to his family medicine physician, now complaining of a painful abscess on his right shoulder that he believed was related to the October 2018 vaccination. Ex. 2 at 1–3. A physical exam confirmed the presence of a 1.5 cm abscess on Petitioner's right upper arm, and the physician performed an incision and drainage ("I&D"), under local anesthesia. *Id*. "Significant pus expressed" following the incision, a sample of which was sent for culture, and Petitioner was prescribed an antibiotic. *Id.;* Ex. 9 at 2.

On February 8, 2019, Petitioner saw an infectious disease physician for follow-up regarding the abscess and its possible etiology. Ex. 3 at 2–4. Despite his I&D, he still "overall" did not feel "entirely well," with increased fatigue and a sense of general malaise. *Id*. Physical exam revealed nothing of concern beyond "a small just slightly erythematous area of indurated skin about 3-4 mm in diameter," at the site where the vaccination had been administered. *Id*. But it was now noted that the I&D culture had been positive for *mycobacterium fortuitum* (known to be associated with skin abscesses) and *propionibacterium* acnes. *Id.* Petitioner was diagnosed with an arm abscess and prescribed a six-week course of antibiotics. *Id*.; Ex. 9 at 2.

No further records regarding Petitioner's treatment were filed. At most, Petitioner has maintained in a witness statement that he continued to feel fatigue from the abscess and related treatment through June 2019, although not long thereafter he felt improvement. Ex. 8 at 2.

"Location Vaccination" and Vaccine Administration Mishandling/Error

A number of facts relating to Location Vaccination's conduct illuminate the circumstances that likely caused Petitioner's abscess. At some time in the fall of 2018 (and hence around the time Petitioner's vaccine was administered), individuals who had received vaccinations from Location Vaccination began reporting that they were developing "abscess nodules" at the injection site. Ex. 7 at 3–4. In response, Vaccination Location management contacted the Centers for Disease Control and Prevention ("CDC") to address the matter, and the CDC confirmed that some identified vaccine recipients had in fact experienced abscesses. Ex. 13 at 25; Ex. 11 at 167–175. In addition, a "Vaccine Adverse Event Reporting System ("VAERS")" report was filed, but Location Vaccination management did not follow CDC advice to test the needles and syringes being used for vaccination. Ex. 7 at 3–4.

In December 2018, as more complaints about post-vaccination abscesses were voiced, the Kentucky Department of Public Health (the "KDPH") instructed Location Vaccination to cease administering vaccines, and thereafter initiated its own investigation. Ex. 11 at 137; Ex. 13 at 3. That investigation included extensive testing of Location Vaccination materials, equipment, and office settings, as well as interviews of company management. Ex. 13 at 3, 5–7, 10–12, 27; Ex. 11 at 35–37, 133. Ultimately, the KDPH's investigation identified "deficiencies in hand hygiene, medical record documentation, and vaccine storage, preparation, administration, and transportation," plus other failures to adhere to CDC safety guidelines for storing or usage of vaccines. Ex. 13 at 21–23, 27. And issues were identified as well relating to the management practices of Location Vaccination (along with the honesty of its principals). *Id.* at 5, 8, 13, 18–19.

Based on its investigation, the KDPH calculated that in the fall of 2018, approximately 100 of the individuals vaccinated by Location Vaccination had experienced a localized reaction, including abscesses, within up to 150 days of vaccination, and a third of these individuals had tested positive for the same bacterium that Petitioner's culture testing had revealed. Ex. 13 at 27. But testing could not confirm the precise source of contamination (i.e., whether it was specifically due to contaminated needles/syringes or a generally-unclean office environment itself). *Id*. at 27–28; Ex. 11 at 33–37. KDPH subsequently issued safety notices to those persons known to have received a vaccine that fall from Location Vaccination, stating expressly that "the vaccine itself did not cause the reactions, but probably something that was done *in preparing or giving the vaccination or possibly an issue with the syringes or needles used*." Ex. 11 at 87 (emphasis added). A statewide health alert sent to medical providers similarly indicated, in warning about the abscess and vaccine reaction outbreak attributed to Location Vaccination, that "[a]ll available evidence point[ed] to an injection safety or practice issue[,] and not a vaccine issue." *Id.* at 125. And a

comparable message was sent to the Kentucky Board of Medical Licensure ("KBML") updating them of their ongoing investigation into the injection-site reactions. *Id.* at 134–36.

The KBML later initiated a disciplinary action against Location Vaccination medical personnel, based on the "outbreak of vaccination reactions . . . likely due to the preparation, storage and/or handling practices" of Location Vaccination. Ex. 7 at 2. And the KDPH continued to state at various points of the investigation that "improper storage and handling of the vaccine[s]," rather than their underlying formulation/content, were the most likely cause of the administration-related issues. Ex. 11 at 164 (February 2019 press release); Ex. 13 at 28 (final KDPH report) (""[c]ontamination could have been from a consistent source within the environment where the syringes were loaded or stored, or a substance that was introduced into the syringes intentionally at the clinic").

II. Procedural History

This Petition was initiated four years ago, along with four others involving the same attorney and alleging a comparable claim.[3] It was assigned to SPU, based on the expectation that damages would be limited, and that the claim otherwise could be expeditiously resolved therein. A year later, however, after records relevant to the claim had been filed, Respondent indicated the intent to seek the claim's dismissal, and that issue was fully briefed by October 2021, with this matter serving as a "test case"[4] for resolution bearing on the other associated matters.

III. Parties' Arguments

Respondent

Respondent highlights the Vaccine Act's language to justify dismissal. He notes at the outset that the Act only permits recovery for injuries that are "associated with" a "vaccine"—terms that are not defined therein. Mot. at 12-13. But at least one decision has defined vaccine to be limited to its substantive ingredients, included therein specifically to prevent or lessen an infectious disease. *Id.* at 13; *Dean v. Sec'y of Health & Hum. Servs*., No. 16-1245V, 2018 WL 3104388, at *9 (Fed. Cl. Spec. Mstr. May 29, 2018). Thus, Respondent reasons, there must be a "causal connection between the petitioner's injury and the effects of the vaccine itself" for a claim to be cognizable. Mot. at 13. And that focus on the vaccine's immune system-impacting properties has in fact been underscored by the Federal Circuit, which has noted (at least in dicta) that injuries

[3] *See Stastny v. Secretary of Health and Human Services* (20-22V), *Atkins v. Secretary of Health and Human Services* (20-333V), *Williams v. Secretary of Health and Human Services* (20-1048), and *Williams v. Secretary of Health and Human Services* (20-1120V). Another set of related claims were also filed in 2020 by different counsel.

[4] The parties have agreed that resolution of one of the related claims could have application to the disposition of the others (subject of course to each side's appellate rights).

"facially unrelated to the vaccine's effects" are not cognizable under the Act, even if otherwise generally *associated* with a vaccine administration event. *Amendola v. Sec'y of Health & Hum. Servs*., 989 F.2d 1180, 1187 (Fed. Cir. 1993) (distinguishing "true" vaccine injury from "a situation in which the direct cause of the injury was a contaminated needle, or the doctor's negligent dropping of an infant patient").

Respondent further contends that his preferred reading of the Act is consistent with its underlying purpose, which in part sought to ensure vaccine production would not be disrupted by tort litigation involving "the small but nevertheless statistically significant incidence of unavoidable injury or death from widespread use of the vaccine." *Amendola,* 982 F.2d at 1185; Mot. at 15-16. It would thus contravene the Act's goals to allow compensation for "an injury that is entirely unrelated to the effects of a vaccine"—even if that injury had some *association* with the act of administration. *Id.* at 16.

Relying on the foregoing, Respondent maintains that the facts underlying this case cannot serve as the basis of a Vaccine Act claim. All of the evidence regarding the proximate reason for Petitioner's abscess establishes negligence on the part of Location Vaccination—whether due to defective/bacteria-contaminated syringes or introduction of contaminated liquids into the vaccination preparation. Mot. at 14. In either case, however, the flu vaccine *itself* did not cause the abscess, and absent such a showing, no recovery under the act should be possible.

On reply, Respondent argues that Petitioner has conceded his injury was not attributable to the effects of the vaccine's contents, but to instead the incidental introduction of bacteria or other contamination. Reply at 2. He reiterates that his reading of the Act (especially in light of *Amendola*) is the more accurate, noting that there has to be distinction between harm caused by a vaccine itself (which clearly is actionable) and injuries sustained in the *course* of vaccination that are not similarly attributable to the vaccine's contents. *Id.* at 3. He rejects Petitioner's argument that language pertaining to "vaccine administrators" in the Act (which Petitioner maintains would include Location Administration) changes the analysis, which remains critically focused on whether the alleged injury was itself properly "vaccine-related." *Id.* at 4. And he denies that the addition of "SIRVA" claims (meaning "shoulder injury related to vaccine administration") to the Vaccine Table supports Petitioner's construction of the Act, deeming that claim instead the product of a *sui generis* determination to permit one kind of administration-associated cause of action, and thus not evidence that negligence by a treater/vaccine administrator can be the basis for a claim. *Id.* at 4–5.

Petitioner

Petitioner's opposition to dismissal includes a recitation of the facts consistent with Respondent's. *See generally* Opp. at 1–10. He affirms that his injury was due to the negligence

and vaccine administration errors of Location Vaccination. *Id.* at 7 ("it is abundantly clear that the vaccine administrator in this case . . . was grossly negligent in regards to not only transporting the vaccine, storing the vaccine, properly drawing the vaccine, but also negligent in actually administering the vaccine to the recipients"). Nowhere does he contend that the flu vaccine's antigenic contents caused some aberrant physiologic reaction leading to his injury.

Nevertheless, Petitioner maintains he states a cause of action under the Vaccine Act. As a baseline matter, he received a covered vaccine, and incurred an injury thereafter that appears "associated" with the vaccination. *Id.* at 9-10. Moreover, under Section 11(a)(3) of the Act, he may bring an action in connection with the conduct of a vaccine *administrator*. In so arguing, he relies on language in the Act that prohibits civil lawsuits against *both* "manufacturers" and "vaccine administrators"—which, he implicitly reasons, means that the misconduct of an administrator should be a permissible basis for a claim. *Id.* at 14–15. He also observes that the Act permits claims based on a "shoulder injury related to vaccine administration," or "SIRVA"—where the injury is the product of a vaccine being injected too high into the upper arm, and thus reflects the Program's recognition that independent negligence can still form the basis for a Vaccine Act claim. *Id.* at 15.

Otherwise, Petitioner contends he can meet all three prongs for a causation-in-fact claim under the standard set by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Opp. at 11–13. And Respondent, he maintains, cannot otherwise prove a "factor unrelated" to the vaccination explains the injury; even if there is some precise uncertainty as to *how* the vaccines became contaminated, there is no other explanation for the outbreak of post-vaccination abscesses except for introduction of a bacterial infection due to vaccine administration negligence. *Id.* at 12–13, 15–16.

IV. Applicable Legal Standards

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[5] There is no applicable Table claim at issue in this matter.

[5] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

The Vaccine Rules promulgated for Program claims do not specifically contain procedures or guidelines for dismissal of petitions purely on legal grounds. Nevertheless, special masters have noted that the practices for dismissal of a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure (and the comparable counterpart of that rule under the Rules of the Court of Federal Claims) have applicability in the context of the Vaccine Program. *See Struck v. Sec'y of Health & Hum. Servs.,* No. 17-1326V, 2018 WL 1514598, at *3 (Fed. Cl. Spec. Mstr. Feb. 9, 2018) (dismissing matter for failure to state a claim upon which relief can be granted); *Herren v. Sec'y of Health & Hum. Servs*., No. 13-1000V, 2014 WL 3889070, at *1 (Fed. Cl. Spec. Mstr. July 18, 2014) (noting that special masters can dismiss a claim as not cognizable, consistent with a 12(b)(6) analysis, because "the standards for pleadings in the Vaccine Program are similar to the standards for pleadings in traditional civil litigation").

ANALYSIS

The Petition raises a question about the Vaccine Act that (surprisingly) has not squarely been resolved over the 30-plus years of the Act's existence: whether *any* claim of injury associated with vaccine administration in the broadest sense is cognizable, even if the injury is shown to be the product of tortious occurrences or circumstances having nothing to do with the body's physical reaction to the vaccine's intended contents. The parties reasonably disagree on this issue, and there

is no clearly-precedential Circuit decision on point. But numerous past special masters have treated comparable injuries as compensable, assuming them to be "vaccine-related"—and this assumption should be followed herein as well, even though Respondent has raised reasonable questions about its ultimate wisdom.

I. Program Treatment of Abscess Cases as Cognizable "Vaccine-Related" Injuries

The basic facts are undisputed. Petitioner received the flu vaccine in October 2018 from Location Vaccination, and thereafter suffered a bacterial infection-induced abscess *due* to that vaccination event generally—but not because of the vaccine's intended components. *See* Mot. at 2–12; Opp. at 2–10.

In several prior Program cases, claimants have not just alleged, but *established*, that a vaccine caused some kind of abscess as a vaccine injury, meeting their *Althen* obligations in the process. *See,* e.g., *Saville v. Sec'y of Health & Hum. Servs*., No. 21-794V, 2023 WL 6192862 (Fed. Cl. Spec. Mstr. Aug. 28, 2023) (flu vaccine caused abscess/cellulitis; causation established in part by dermatologic expert report, unopposed by Respondent); *Skinner-Smith v. Sec'y of Health & Hum. Servs*., No. 14-1212V, 2022 WL 4116896 (Fed. Cl. Spec. Mstr. Aug. 15, 2022), *reconsideration den'd*, 2022 WL 13461862 (Fed. Cl. Spec. Mstr. Sept. 9, 2022) (vaccines caused cellulitis but not subsequent chronic fatigue syndrome); *Pociask v. Sec'y of Health & Hum. Servs.,* No. 96-569V, 1999 WL 199053 (Fed. Cl. Spec. Mstr. Mar. 24, 1999) (tetanus vaccine not shown to cause fibromyalgia, but Respondent conceded it had caused an abscess, which the special master deemed the basis for a damages award).[6]

Accordingly, the general concept that a vaccination might produce an injury comparable to what has been alleged herein is mostly uncontroversial (although the facts of this case are different).

II. "Vaccine Cleanliness" Claims Involving an Abscess as the Injury Do Not Appear to Fall Outside the Scope of the Vaccine Act

Although the record establishes Petitioner experienced a post-vaccination abscess, the same record also strongly supports the conclusion that Petitioner's injury was attributable *solely* to contamination associated with the vaccine's administration—which in turn was caused by Location Vaccination's negligence. Indeed, the state agency investigations into Location Vaccination repeatedly proposed, and ultimately determined, that the vaccine's intended

[6] In addition, many cases alleging a vaccine-caused abscess have settled (although such cases have limited precedential value as a result). *See,* e.g., *Neighbors v. Sec'y of Health & Hum. Servs*., No. 20-1768V, 2022 WL 1873818 (Fed. Cl. Spec. Mstr. Apr. 22, 2022); *Jackson v. Sec'y of Health & Hum. Servs*., No. 17-682V, 2018 WL 2772347 (Fed. Cl. Spec. Mstr. Mar. 27, 2018); *Kranz v. Sec'y of Health & Hum. Servs*., No. 15-0196V, 2015 WL 4608102 (Fed. Cl. Spec. Mstr. July 13, 2015).

components, and associated immunologic effects, *were not causal* of the injuries so many incurred. *See,* e.g., KDPH Final Report, filed as Ex. 15 (ECF No. 1-17) (Kentucky Department of Public Health's report concluding that the vaccines were contaminated either from the environment where they were loaded or stored, or intentionally contaminated at the Location Vaccination clinic). I am unaware of any case where the evidentiary connection between third-party negligence and a vaccine injury was so unmistakable—with no evidence the vaccine's antigenic components resulted in physiologic harm. Should such a claim be deemed to "fall out" of the Program's scope, even if abscess injuries have been compensated in prior matters?

To bulwark their contentions about the claim's foundational tenability, both sides cite a dated Federal Circuit opinion, *Amendola*—but it can be read as supporting *either* view.

In *Amendola,* the Federal Circuit reviewed whether a special master's dismissal of a claim was legally warranted, affirming that determination. *Amendola,* 989 F.2d at 1187. Dismissal had been based on the Program's preclusion of certain claims due to associated shielding of vaccine manufacturers and/or administrators. Before the Vaccine Act petition had been initiated, a comparable claim had been tried unsuccessfully in New York state court against the pediatrician responsible for the vaccine's administration. *Id.* at 1181. That doctor was alleged to have made a negligent medical decision in administering a vaccine to a minor, aware that a prior dose of the same vaccine had prompted an injurious reaction but nevertheless proceeding with a second dose. *Id.* Thus, while professional negligence in the treatment decision was the heart of that claim, the adverse effect of the vaccine was the proximate cause of the injury (as opposed to a contaminated needle).

Respondent maintained that once the state court matter was resolved, a second claim arising from the same set of facts could not be brought under Section 11 of the Act, given the Act's provisions shielding certain entities, like manufacturers or vaccine "administrators," from suit (in order to ensure such claims were initiated in the Court of Federal Claims). *Amendola,* 989 F.2d at 1181. In opposing dismissal, the *Amendola* petitioners argued (among other things)[7] that the Act did not "expressly and specifically describe the fact pattern of their case," and therefore did not bar them from pursuing a Vaccine Act claim despite the first case's dismissal, because "a malpractice action for a doctor's misconduct" was not the kind of claim the Act covered (and hence a prior such claim could not preclude someone from later seeking Vaccine Act liability based on the same set of circumstances). *Id.* at 1183, 1185. Rather, the Act was intended to shield vaccine manufacturers or administrators "only from 'strict liability' claims," and not from negligent conduct, even if the claim was otherwise "related" to vaccine administration in some way. *Id.* at 1186.

[7] Some of the issues in *Amendola* plainly have no bearing on the present circumstances, such as when the claim accrued (pre or post-enactment of the Vaccine Act). The *Amendola* petitioners also contended that doctors who (via vaccination) caused a vaccine injury were not actual "administrators" as the term is defined in the Act. *Amendola,* 989 F.2d at 1186.

The Circuit rejected the argument, finding that "erroneous judgment calls by the administrator" of a vaccine, or even the "negligent contamination" of a vaccine dose, were claims that would need to be initiated in the "Vaccine Court." *Amendola*, 989 F.2d at 1186. This would seem, at least facially, to *support* the viability of Mr. Silvers's claim herein—were it not for what the Circuit said next. For (albeit in *dicta*) the panel *also* opined that "negligence **facially unrelated to the vaccine's effects"** would not fall into the classification of "vaccine-related," and therefore could be pursued independently of the Act (as the *Amendola* petitioners wished to do). *Id.* at 1187 (emphasis in original). As examples, the Circuit proposed "a situation in which the direct cause of the injury was a contaminated needle, or the doctor's negligent dropping of an infant patient . . . ." *Id.* The injury that the *Amendola* petitioners had tried in state court against the physician, by contrast, was attributable to the vaccine itself. Accordingly, full resolution of the prior action precluded the subsequent matter proceeding in the Vaccine Program.

To some extent, *Amendola* seemed to construe the Act's use of the term "vaccine-related" as distinguishable from "iatrogenic," or *treatment-associated* harms, deeming the latter incongruent with what can be litigated directly in the Program. *Amendola,* 989 F.2d at 1186 ("there is some support in the statute and legislative history for the proposition that the Act was not drafted with the problem of iatrogenic injury in mind"); *see also* H.R. Rep. No. 908, 99th Cong., 2d Sess. 26, *reprinted in* 1986 U.S. Code Cong. & Admin. News 6344, 6348 (two principal concerns behind Vaccine Act's creation were "(a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market"), and Senate Comm. On Labor and Human Resources, National Childhood Vaccine Improvement Act of 1986, S. Rep. No. 483, 99th Cong., 2d Sess. at 5 (focusing on remedies with respect to manufacturers). The Act sought only to provide a remedy for adverse physiologic impact of vaccines (since it was that sort of claim that would be brought against manufacturers), and not any and all negligence *associated* with a vaccination.

Since *Amendola*, the Federal Circuit has not again discussed whether third-party negligence associated with a vaccine's administration would constitute an actionable claim. However, the Court of Federal Claims, and some special masters as well, have in a few instances observed the existence of the question, appearing to concur that at least *some* level of negligence independent of vaccination would not be cognizable as a Vaccine Act claim—but also allowing for this sort of claim to proceed.

Almost 20 years ago, for example, the Court was confronted with an issue parallel to what was at stake in *Amendola*: whether a state-court negligence claim arising out of a vaccination event could be considered a "vaccine-related injury" under the Act (such that a Vaccine Act claim would

preclude it), and concluded it was. *Aull v. Sec'y of Health & Hum. Servs.,* 65 Fed. Cl. 400 (2005).[8] But *Aull* contemplated the same kinds of questions that seem answered by the *Amendola* dicta. Thus, *Aull* noted that it "makes sense in light of the purpose of the [Vaccine Act]" to differentiate between "whether the injury alleged in the alternative proceeding flows out of the effects of the vaccine itself" versus unrelated negligence only broadly associated with the vaccination. *Aull,* 65 Fed. Cl. at 405. *Aull* concluded that "if the injury is associated with the receipt of the vaccine *qua* vaccine," the Act provides the sole basis for the claim—but does not otherwise prohibit state-level claims involving the kinds of negligence instances listed in *Amendola. Id.*

A few years before *Aull,* a special master was also confronted with a comparable question of the Act's scope, in the context of a claim that a child's autism was caused by the thimerosal preservative contained in the vaccine. *Leroy v. Sec'y of Health & Hum. Servs.,* No. 02-392V, 2002 WL 31730680 (Fed. Cl. Spec. Mstr. Oct. 11, 2022). Unlike *Amendola* or *Aull, Leroy* did not involve the question of a pending state court matter and whether the Act precluded it, but instead the more central question of whether some kinds of claims not involving injury directly due to the vaccine's impact on the body could be tenable. *Leroy* found the claim *did* arise under the Act, since the preservative had been intentionally included as a component of the vaccine in question.[9] *Leroy,* 2002 WL 31730680, at *12–16. But the special master also took notice of the fact that in arguing for the Act's coverage of the claim, *Respondent* had noted that the Program properly included even claims "related to misadventures from the act of administering the vaccine"—which would *include* abscess injuries. *Id.* at 12 (citations omitted).

Accordingly, this handful of decisions suggests that some kinds of "vaccine-associated" claims would not fall within the ambit of the Act. At the same time, however, these cases demonstrate the extent to which things not pertaining directly to the impact of vaccination on the human body can constitute a cognizable claim—with no Circuit pronouncement squarely defining what is or is not actionable (although *Leroy's* dicta seems to envision the legitimacy of abscesses as a vaccine injury).

Petitioner offers other rationales for his contention—none of which are particularly persuasive. First, he proposes that the Act plainly considers "administrators" of vaccines (along

[8] The *Aull* petitioners contended that a physician improperly administered a vaccine to a child with a preexisting condition, which was subsequently exacerbated by the vaccination—hence the kind of circumstances in which "[t]he injury and death . . . are associated with the physical effects of the vaccine," meaning a parallel state court action was barred by the Act. *Aull,* 65 Fed. Cl. at 406.

[9] Notably, *Leroy* also addressed whether the preservative component was a "contaminant," since the Act expressly excludes injuries "associated with an adulterant or contaminant intentionally added" to the relevant vaccine. Section 33(5). Although the injury in this case is also likely attributable to contaminants (even if it is unclear *how* precisely they were introduced—i.e., via an unclean needle or as extraneous bacteria-containing fluids in the vaccine syringe), the record does not show that they were more than negligently introduced to the vaccination process, nor does Respondent argue otherwise. I therefore do not find that this exception applies to the Petitioner's allegations.

with manufacturers) to be shielded from liability for injuries recognized by the Act (*see,* e.g., Section 11(a)(2)(A)). But this presupposes that the Act permits *any* negligence-based claims to proceed—when (as Respondent argues) this may not be so in the first place. It is not necessarily the case that claims against a vaccine administrator are, by definition, properly and/or exclusively litigated in the Program; the Act's liability "shield" could instead merely function to force petitioners *first* to litigate a vaccine injury claim herein, reserving any secondary claim involving distinguishable negligence for later. *See* 42 USCA § 300aa-21 (outlining Petitioner's options after the conclusion of their case).

Second, Petitioner notes the existence of the SIRVA Table claim as evidence that Program claims can involve "vaccine-associated" negligence. SIRVA injuries are of course predicated on human error in vaccine administration, occurring when a covered vaccine is injected too high in the deltoid, and/or too close to the shoulder. 42 C.F.R. § 100.3(c)(10) (SIRVA pain and range of motion issues "are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction"). However, SIRVAs occur *ultimately* because a vaccine's *contents* are introduced into a space where the vaccine is not intended to go, rather than intramuscularly, thereby causing an immediate and painful inflammatory reaction. *Rance v. Sec'y of Health & Hum. Servs.*, No. 18-222V, 2023 WL 6532401, at *14 (Fed. Cl. Spec. Mstr. Sept. 11, 2023) (expert testifying on prong one in non-Table SIRVA claim and opining that it is "the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction" that is the primary feature of SIRVA). Thus, SIRVA claims *do* involve an aberrant vaccine reaction—not merely administrator negligence.

In addition, SIRVAs are *Table-defined* injuries, in which the negligent misadministration is not *itself* something that must be factually proven—and hence that matter is not litigated in any such claim, but instead is *presumed,* with the fact questions to be resolved centering on the nature of the injury. (In fact, this is in keeping with the no-fault nature of the Program itself, which does not involve determinations of relative culpability except in limited circumstances specific to vaccine effects). Thus, SIRVA actually provides an "exception that proves the rule" explanation for why the current claim might not be cognizable, since even in this context the injury turns mainly on the vaccine's contents as causing the injury—not the nature or extent of misadministration. It is yet another kind of claim in which issues of negligence *are not litigated* by the Program.[10]

Thus, Petitioner's specific arguments in favor of the tenability of this claim are not particularly robust or persuasive. And Respondent reasonably notes that given the record evidence,

[10] Indeed, there is no SIRVA Table element requiring proof of misadministration, but instead only that SIRVA best explains the injury *in retrospect*. 42 C.F.R. § 100.3(c)(10)(iv). Special masters do not adjudicate the precise location of a vaccine's administration, in order to ascertain the likelihood of misadministration (and it would be likely improper for them to take up such a question—even in the context of a failed Table SIRVA).

there is no way to find that the "vaccine *qua* vaccine" explains Petitioner's abscess. This matter therefore walks the very edge of what the Program recognizes as a compensable matter.

However—and despite good faith, reasoned grounds to reject the action entirely, as argued by Respondent—I find herein that the claim is cognizable. I base my determination on the fact that despite the possibility that the Federal Circuit (if directly confronted with the question) could amplify the dicta from *Amendola* into a bright-line rule prohibiting negligence-based vaccine injuries, the Program *to date* (as reflected by the special master determinations noted above) has consistently treated claims involving the "cleanliness" of vaccine needles/syringes, or even the circumstances of administration more broadly, to be actionable, "vaccine-related" injuries, allowing compensation even without determining that the vaccine's antigenic components caused harm.

Given that history, I am reluctant to differentiate between claims where a vaccine's immunologic/physiologic effects were alleged harmful (which constitute the vast majority of Program claims) and petitions involving even stark instances of obvious, independent negligence—as here. To do so would be to reject the findings of numerous prior cases—and on the basis of unclear law as well. While prior Program thinking on a given topic is not carved in stone, and may well be erroneous, it is worthy of respect, and should be followed in most instances if possible. Here, I prioritize such considerations over a novel argument that, although facially appealing, may be drawing a distinction that is not legally sound in the end.

Unquestionably, there exists a category of vaccine administrator negligence so obviously independent that it could not be recast as a compensable Program claim, even though it might *generally* be deemed "vaccine-related."[11] But this claim presents a closer case, and thus is more reasonably deemed to be cognizable by the Act—*if barely*.

III. Petitioner is Entitled to Compensation

Even though the facts at issue plainly establish independent negligence as the cause of Petitioner's injury, the elements of a non-Table claim under the *Althen* standard are met. First (and relying on the many prior cases addressing comparable injuries), I find it is established that unclean conditions associated with a vaccination—whether due to the needle or contaminants introduced into the body with the vaccine—"can cause" an abscess. Opp. at 11–12. Admittedly, Petitioner has not yet offered expert support for this *Althen* prong, but it is far from the case that

[11] For example, suppose a medical treater or other administrator, preparing to vaccinate an individual, hurled a syringe loaded with vaccine at a person, and the needle (or even just the syringe itself) struck the patient, causing an injury. Those facts literally describe a "vaccine-related" injury—but it would be much easier to declare that fact pattern as alleging a claim falling outside the confines of the Act (the vaccine was never actually administered, and the treater's conduct directly caused the injury). Clearly not every kind of negligence *associated* with the event of a vaccination can be folded into a Vaccine Act claim, simply on the basis of the Act's shielding provisions and vague terminology.

every Program petition requires an expert report simply because a causation-in-fact claim is alleged. Section 13(a)(1) ("[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion") (emphasis added). Indeed, there is no one specific type of evidence required to prove causation—and to define a class of evidence as a prerequisite would be to impermissibly raise a claimant's burden of proof. See *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (petitioners may satisfy the first *Althen* Prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory) (citing *Capizzano v. Secretary of Health & Human Services*, 440 F.3d at 1325–26 (Fed. Cir. 2006) .[12] Rather, I can rely on other evidence to resolve this *Althen* prong—including prior consistent special master determinations involving abscess injuries - just as I might dismiss a claim for asserting a causation theory that has been repeatedly rejected. See *Hughes v. Sec'y of Health & Hum. Servs.*, No. 16-930V, 2021 WL 839092, at *23 (Fed. Cl. Spec. Mstr. Jan. 4, 2021) ("it is equally the case that special masters reasonably draw upon their experience in resolving Vaccine Act claims") *citing Doe v. Sec'y of Health & Hum. Servs.*, 76 Fed. Cl. 328, 338–39 (2007)(("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the *expertise and experience to know the type of information that is most probative of a claim*") (emphasis added).

The remaining two *Althen* prongs are also met. It is undisputed that some form of vaccine cleanliness/contamination did likely cause Petitioner's injury. Further, the timeframe in which the injury arose was accepted by independent state investigations as reasonable when measured against the date of vaccination. See Ex. 13 at 27 (KDPH investigation concluding that 100 individuals vaccinated by Location Vaccination experienced localized reactions within 150 days of vaccination). And I cannot find on this record that Respondent has established a "factor unrelated" was causal, exclusive of the vaccination. Again—the vaccination *was* the reason for the injury (even though its intended contents were plainly not causal), meaning Respondent cannot exclude it as potentially causal, as he must to prevail in establishing factor unrelated. *White v. Sec'y of Health & Hum. Servs.*, No. 20-1319V, 2023 WL 4204568, at *15 (Fed. Cl. Spec. Mstr. June 2, 2023), *mot. for review den'd,* 168 Fed. Cl. 660 (2023); *appeal docketed,* No. 20-1319 (Fed. Cir. 2024). I could only find otherwise if I accepted Respondent's contention about the distinction between negligence associated with vaccination and injuries due to the biologic impact of the vaccine—and as well-reasoned as that argument is, the Program's ready willingness to compensate other abscess-injured parties overrides Respondent's reading of the Act.

[12] Indeed, there are many circumstances in the Program in which an expert report need not be offered in the causation context. For example, for a claim of GBS after the flu vaccine that could not satisfy the 3-42 day Table onset, I would never order a petitioner to offer an expert to establish that the flu vaccine "can cause" GBS.

CONCLUSION

Although this claim is based on vaccine administration-related errors having nothing to do with the vaccine's contents and specific biologic impact, it is (perhaps perversely) viable under the Act – and the facts that so fully demonstrate third-party negligence as the total cause of the injury do not push this claim out of the Program. Petitioner is accordingly entitled to compensation. The parties shall be contacted shortly to discuss a process for determining damages in this and the other related claims.

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master